

**REMARKS**

This Application has been carefully reviewed in light of the Final Office Action mailed May 17, 2006. At the time of the Final Office Action, Claims 138-148 were pending in this Application. Claims 138-148 were rejected. Claims 138, 139, and 148 have been amended. New Claims 152 and 153 have been added. Applicant respectfully requests reconsideration and favorable action in this case.

As a preliminary matter, Applicant thanks the Examiner for withdrawing several prior rejections.

**Rejections under 35 U.S.C. §§ 102 and 103 over Nakazawa**

The Office Action indicates that Claims 138-141 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Japanese Patent Application Publication No. 62153220, formal translation, by Shinzo Nakazawa and Satoshi Hisano ("Nakazawa"). Claims 138-147 stand rejected under 35 U.S.C. §103(a) as allegedly being obvious over Nakazawa and Acharya. Claim 148 stands rejected under 35 U.S.C. §103(a) as allegedly being obvious over Nakazawa and Vandelli.

Applicant respectfully traverses these rejections and submits the cited art does not teach or suggest all of the elements of the claimed embodiment of the invention. More specifically, Nakazawa, whether considered alone or in combination with Acharya and/or Vandelli, fails to provide an enabling disclosure of compositions that are "free of precipitates or particles."

Applicant has made the following statement about a particular composition according to Nakazawa:

Upon heating, the solution with amyloextrin became mostly clear with some **undissolved matter**. Declaration dated May 14, 2004, Section 6(A)(i), Page 4 (emphasis added).

The observed undissolved matter included visible precipitates and/or particles, such that this composition of Nakazawa cannot be said to be "free of precipitates or particles" as recited by amended claims 138 and 148. Therefore, Nakazawa fails to enable preparation of the claimed aqueous solutions. Acharya and Vandelli likewise fail to enable preparation of the claimed solutions. Accordingly, Applicant respectfully requests withdrawal of these rejections.

**Rejections under 35 U.S.C. §§ 102 related to cyclodextrin**

Claims 138-141 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by *Improvement of Ursodeoxycholic Acid Bioavailability by 2-Hydroxypropyl- $\beta$ -Cyclodextrin Complexation in Healthy Volunteers*, by R. Panini et al., Pharmacological Research, Vol. 31, No. 3/4, 1995 ("Panini"). Claims 138-141 also stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,534,505 issued to Josef O. Widauer ("Widauer"). In addition, Claims 138-141 stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by *Improvement of Water Solubility and Dissolution Rate of Ursodeoxycholic acid and Chenodeoxycholic acid by Complexation with Natural and Modified  $\beta$ -cyclodextrins*, by C.A. Ventura et al., International Journal of Pharmaceutics, Vol. 149, pp. 1-13, 1997 ("Ventura"). Applicant respectfully traverses these rejections and submits the cited art does not teach all of the elements of the claimed embodiment of the invention.

Claim 138 recites "a second material selected from the group consisting of an **aqueous soluble starch conversion product**, an aqueous soluble non-starch polysaccharide, and combinations thereof" (emphasis added). Although cyclodextrins may be obtained from starch, they are not "aqueous soluble starch conversion product[s]" as recited by claims 138. For example, according to the specification at page 22, line 3 et seq., "aqueous soluble starch conversion products are defined as .... [having] at least one reducing end and one non-reducing end." As demonstrated by McNaught, Lehninger, Horton, and Schmid, which were included with the last Office Action, cyclodextrins do not have a reducing end. *See, e.g.,* McNaught, §§ 36.2, 37.1, and 37.4. Therefore, since Panini, Widauer, and Ventura each fail to teach an "aqueous soluble starch conversion product" as claimed, Applicant respectfully requests withdrawal of these rejections.

**CONCLUSION**

Applicant has now made an earnest effort to place this case in condition for allowance in light of the amendments and remarks set forth above. Applicant respectfully requests reconsideration of the pending Claims.

Applicant believes there are no further fees due at this time, however, the Commissioner is hereby authorized to charge any additional fees necessary or credit any overpayment to Deposit Account No. 50-2148 of Baker Botts L.L.P.

If there are any matters concerning this Application that may be cleared up in a telephone conversation, please contact Applicant's attorney at (512) 322-2647.

Respectfully submitted,  
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